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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/670,405

09/24/2003

Susan I. Shelso

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,405	Applicant(s) SHELSON, SUSAN I.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 11-17, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frid et al (US 6159228) in view of Roberts et al (US 5984964). Frid discloses an applicator for a stent comprising an outer shaft 7 and an inner shaft 5 slidably disposed within and concentric with the outer shaft, a rigid inner member 11, the proximal end of the inner rigid member is coupled to the proximal end of the inner shaft, a catheter 9 coupled to the rigid inner member, and an exterior tube 12 coupled to the outer shaft. The inner and outer shafts include gripping portions. The distal end of the catheter is covered by the sheath in the first position and uncovered by the sheath in the second position. See Figs. 5, 6.

3. Claims 11, 19 differ from Frid in calling for the inner and outer shaft portions to have a second position wherein the distal end of the inner shaft engages the distal end of the outer shaft. Roberts teaches a device similar to that of Frid, but including a second position wherein the inner shaft 12 distal end engages the outer shaft distal end so that the user can be certain that the stent has been released from the outer sheath member. See Fig. 1A. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Frid to include a second position as taught by Roberts so that the user can know when the stent has been released from the outer sheath.

4. Claims 11, 19, 20 further differ from the teachings above in calling for the exterior tube to be stepped. In the instant application the outer tube is stepped to receive the distal end of the outer shaft while still being slim enough at the distal portion to be easily inserted into the

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vasculature. Instead of being stepped at the proximal end to accommodate the outer shaft member, Frid teaches that the exterior tube is received within the distal end of the outer shaft member. Both are known methods of attaching two components such as a tube and a hub while maintaining the necessary small diameter at the distal end of the tube. Therefore, it would have been an obvious matter of design choice to include a stepped exterior tube wherein the larger diameter portion receives the hub in the device of Frid instead of having a constant diameter tube wherein the distal end is received by the hub.

5. Claims 10, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable Frid in view of Roberts, in view of DiCaprio et al (US 6176843). Claims 10, 18 differ from Frid in view of Roberts in calling for a valve to flush air from the sheath. DiCaprio teaches a device for delivering a stent having a valve 34 that allows air to be forced out of the lumen to prevent the possibility of an air embolism forming. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Frid in view of Roberts to have a valve as taught by DiCaprio to allow air to be purged from the lumen.

Response to Arguments

6. Applicant's arguments filed 12/30/08 have been fully considered but they are not persuasive. Applicant argues that omission of the interposed flexible pusher element while retaining the function is indicia of unobviousness. The examiner does not necessarily agree with this assertion because there are often different elements that achieve the same function, neither being desirable over the other, and one of skill in the art would recognize them to be obvious equivalents. However, this is not the point at issue, because the claim contains the "open" term

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comprising, meaning the prior art must disclose all the claimed elements but may further include any number of additional elements and still meet the claim.

7. Applicant points to Fig. 1A of Roberts to show that there is a space between the handles and points out that the gaps are 37% different. First, drawings are not to scale so applicant's arguments regarding the relative measurements of the components is irrelevant. Secondly, the claim requires that the distal end portions be engaged. The distal end portions are interpreted to be the entire handle portion at the distal end of each member, and these end portions are clearly engaged with each other as shown in Fig. 1A. Engaged does not have to mean that the portions are flush against each other, just that they are physically touching in some way.

8. Applicant argues that the instant invention is different from the prior art because it allows the user to choose components while Frid does not appear to have this feature. This is not a claimed feature.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763